K972242

510(k) SUMMARY

JAN 16 1998

Submitter

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Date Prepared: June 13, 1997

Name of Device

Trade Name: "Reveal™ Insertable Loop Recorder" (ILR) System. The system is composed of the Model 9525 implanted recorder and the Model 6190 Activator. The Model 9802E Reveal software, Model 9790 programmer and Model 9766A telemetry head are also part of the system.

Common Name: insertable loop recorder

Classification Name: The Reveal Insertable Loop Recorder (ILR) system is a combination of existing devices. The classification names and numbers of these devices are:

- "Telephone electrocardiograph transmitter and receiver" (870.2920) (Class II)
- "Implantable pacemaker pulse generator" (870.3610) (Class III)

Predicate Devices

Table 1. Reveal ILR System - Predicate Devices

Product	Features Similar to the Reveal ILR System
Instromedix King of Hearts Express® 3X™ Model 5328-00 (cardiac event recorder-looping memory)	• Ambulatory event recorder • Continuous ECG recording • Looping memory • Pre- and post-event storage • Patient-activated
Medtronic Minix Model 8341M (single-chamber implantable pulse generator)	• Implantable • Dimensions • Subcutaneous electrode (in unipolar mode) • Programmable via a programmer unit • Transmit real time ECG waveform • Data retrieval (radio-frequency telemetry)

Device Description

System Description

The Reveal ILR system is designed to record and store subcutaneous electrocardiogram (ECG) during symptomatic events. The system consists of the Model 9525 implanted recorder and the Model 6190 Activator. A Medtronic Model 9790 programmer equipped with a Medtronic Model 9766A radio frequency telemetry head and Model 9802E software is required for programming and retrieving data from the recorder.

Model 9525 Implanted Recorder

The implanted recorder is a single-use, programmable device which is constructed of the same tissue-contacting materials used in Medtronic pacemakers. The implanted recorder is designed for long-term subcutaneous implantation. The implanted recorder is programmed using a Medtronic Model 9790 programmer. It continually records subcutaneous ECG into its looping memory and stores recorded ECG when signaled by the Activator.

Model 6190 Activator

The Activator is a hand-held, battery-operated telemetry device that communicates with the implanted recorder through the skin. It is used to signal the implanted recorder to store ECG recorded during a symptomatic event, for later retrieval and evaluation. The Activator is designed to be used during symptoms or immediately after symptoms. When the Activator is placed over the implanted recorder and the Activator button is pushed, the implanted recorder stores the ECG recorded during a pre-determined period of time before and after the Activator is used.

Stored ECG is retrieved via telemetry using a Medtronic programmer. The retrieved ECG can be viewed on the programmer screen, printed, or saved to disk. Stored ECG is erased and the recorder is restarted for continued use with a Medtronic programmer.

Programmer

Reveal Model 9802E software is loaded onto the Medtronic Model 9790 programmer. The programmer, with the Model 9766A radio frequency (RF) telemetry programming head, is used to communicate with the implanted recorder. The programmer uses radio frequency (RF) telemetry to transmit to and receive data from the implanted recorder and is used to program parameters of the implanted recorder, and to retrieve and display stored events for analysis.

Software

Reveal Model 9802E software is run from the Model 9790 programmer. It allows the clinician to program parameters of the recorder and to retrieve stored events for analysis. The clinician may select one of four modes for data storage. When the device memory is full, the software is used to erase stored events and restart recording for continued use.

When event(s) are stored in the implanted recorder's memory, the clinician may retrieve these event(s). The clinician can view the stored event on the programmer screen or print all or portions of the waveform to the programmer printer or to a full size external printer.

The events can also be saved on a diskette for later use. This allows the clinician to read the events from diskette at a later time when the patient and device are not present. At that time, events can be analyzed on the programmer screen or printed.

Packaging

Two package configurations are available. The ILR system package contains the implanted recorder, the Activator, and the product information manual. A replacement Activator is available in the other package configuration. Both package configurations were fully validated.

Intended Use

The Medtronic Model 9525 Reveal Insertable Loop Recorder is an implantable, patient-activated monitoring system that records subcutaneous ECG and is designed for diagnostic evaluation of patients who experience transient symptoms that may suggest a cardiac arrhythmia.

Technological Characteristics

The technology used with the Reveal ILR system is similar to several devices currently available on the market. The table on the following page outlines the functional similarities between the Reveal ILR system and the identified predicate devices.

Device Feature	Reveal™ ILR	Instromedix King of Hearts	Medtronic Minix™ IPG
ECG Recorder	Yes	Yes	No
Real-time Waveforms	Yes	No	Yes
Looping Memory	Yes	Yes	No
Implantable	Yes	No	Yes
Pre and Post Event Storage	Yes	Yes	No
Subcutaneous Electrode	Yes	No	Yes (in unipolar mode)
Patient-Activated	Yes	Yes	No
Implantable Battery	Yes	No	Yes
Total Storage Time	42 min.*	5 min.	No
Maximum Single Event Storage Time	42 min.	5 min.	N/A
Storage Modes	4 modes	Programmable	N/A
Number of Events	1 or 3	Up to 60	N/A
Data Retrieval	Radio-frequency telemetry	Transtelephonic or audio-coupling	Radio-frequency telemetry
Bandwidth	0.85-32 Hz	0.05-30 Hz	N/A
Sampling Rate	100 Hz	218 Hz	N/A
Volume	8 cc	N/A	10.4 cc
Mass	17 g	N/A	24.8 g
Dimensions	61 x 19 x 8 mm	N/A	50x14x6 mm

*ECG waveforms stored in modes with a total storage time to increase storage time. Data sampled at 100Hz is stored to memory at 50Hz.

Summary of Studies

The following studies were performed to ensure that the Reveal ILR system meets all of its design and performance requirements.

In Vitro/Bench Testing

To evaluate the Reveal ILR system, the following in vitro testing was completed:

- Model 9525 implanted recorder testing (hybrid qualification testing, electromagnetic compatibility testing, mechanical testing, and battery testing)
- Model 6190 Activator testing
- Package testing

The Reveal ILR system passed all of the in vitro requirements.

In Vivo Canine Testing

Two comparative studies of the Reveal ILR system were performed with canines. One study compared the Reveal ILR system to a surface ECG monitor. The other study compared the Reveal ILR system to a surface monitor and two competitive devices currently available: the Instromedix King of Hearts Express® 3X™ and the Instromedix HeartCard 3X™ (cardiac event recorders). The data generated by these studies demonstrate that the Reveal ILR system is safe and provides ECG information which is substantially equivalent to that provided by the surface monitor and cardiac event recorders.

Biocompatibility Information

Biocompatibility testing was not required because blood-contacting materials of the Reveal ILR implanted device are the same as the Medtronic Minix implantable pulse generator.

Sterilization Validation

The Model 9525 implanted recorder is sterilized using a 100% Ethylene Oxide (EtO) sterilization process. A process appropriate for sterilizing the Model 9525 implanted recorder was validated.

Conclusion

The testing described above provides reasonable assurance that the Reveal ILR system will perform as intended when used in accordance with its labeling. Additionally, based on similarities in design, materials, in vitro test data and canine in vivo electrical performance, Medtronic considers the Reveal ILR system to be substantially equivalent to these pre-regulation devices: the Instromedix King of Hearts Express 3X, and the Medtronic Minix implantable pulse generator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 1999

Ms. Nora K. Hadding
Cardiac Pacing Business
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, MN 55432-3576

Re: K972242
The Reveal™ Insertable Loop Recorder System including
the Model 9525 Implantable Recorder and
the Model 6190 Patient Activator
Regulatory Class: II (two)
Product Code: 74 MXC
Dated: October 17, 1997
Received: October 20, 1997

Dear Ms. Hadding:

This letter corrects our substantially equivalent letter of January 16, 1998, regarding the Reveal™ Insertable Loop Recorder System. We believe that the product code and regulatory classification of the device should have been 74 MXC/II(two).

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

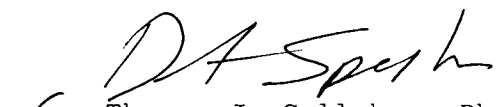
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS

inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): N/A K972242

Device Name: Reveal™ Insertable Loop Recorder System

Indications For Use: The Medtronic Model 9525 Reveal™ Insertable Loop Recorder is an implantable, patient-activated monitoring system that records subcutaneous ECG and is indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular and Neurological Devices
510(k) Number

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)